DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 13 April 2006, which claims benefit priority to International Application PCT/SG2004/00340, filed 14 October 2004, which claims priority to US Provisional Patent Application 60/512,479, filed 17 October 2003.

2. **Claims 1-32** have been canceled by preliminary amendment.

3. **Claims 33-52** are currently pending and have been examined.

Drawings

4. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings contain photographs as well as black borders, and are generally illegible. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected

drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claims 38, 39 and 47** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38 and 39 are dependent on claim 37, but claim 37 does not require the limitation necessary for claims 38 and 39. It is unclear from the claims as written, as to what the invention would involve in claims 38 and 39 if claim 37 is fulfilled by limitation *a.* or *b.,* but not limitation *c.*

Similarly, claim 47 is dependent on claim 46, but claim 46 does not require the limitation necessary for claim 47. It is unclear from the claims as written, as to what the invention would involve in claim 47 if claim 46 is fulfilled by limitation *a., b., d., e., f.* or *g.,* but not

limitation *c.*

Appropriate clarification is required.

Information Disclosure Statement

7. The information disclosure statement (IDS) submitted on 19 June 2006 has been considered by the Examiner.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. **Claims 45, 46, 48, 49, 51 and 52** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Regarding **claims 45, 46, 48, 49, 51 and 52** a claimed process is eligible for patent

protection under 35 U.S.C. § 101 if:

> (1) It is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See Benson, 409 U.S. at 70 ('Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines.'); Diehr, 450 U.S. at 192 (holding that use of mathematical formula in process 'transforming or reducing an article to a different state or thing' constitutes patent-eligible subject matter); see also Flook, 437 U.S. at 589 n.9 ('An argument can be made [that the Supreme] Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a 'different state or thing' '); Cochrane v. Deener, 94 U.S. 780, 788 (1876) ('A process is...an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.').[7] A claimed process involving a fundamental principle that uses a particular machine or apparatus would not pre-empt uses of the principle that do not also use the specified machine or apparatus in the manner claimed. And a claimed process that transforms a particular article to a specified different state or thing by applying a fundamental principle would not pre-empt the use of the principle to transform any other article, to transform the same article but in a manner not covered by the claim, or to do anything other than transform the specified article. (*In re Bilski, 88 USPQ2d 1385, 1391 (Fed. Cir. 2008))*

Also noted in *Bilski* is the statement, "Process claim that recites fundamental principle, and that otherwise fails 'machine-or-transformation' test for whether such claim is drawn to patentable subject matter under 35 U.S.C. §101, is not rendered patent eligible by mere field-of-use limitations; another corollary to machine-or-transformation test is that recitation of specific machine or particular transformation of specific article does not transform unpatentable principle into patentable process if recited machine or

transformation constitutes mere 'insignificant post-solution activity.'" (*In re Bilski, 88 USPQ2d 1385*, 1385 (Fed. Cir. 2008)) Examples of insignificant post-solution activity include data gathering and outputting. Furthermore, the machine or transformation must impose meaningful limits on the scope of the method claims in order to pass the machine-or-transformation test.

It is also noted that the mere recitation of a machine in the preamble in a manner such that the machine fails to patentably limit the scope of the claim does not make the claim statutory under 35 U.S.C. § 101, as seen in the Board of Patent Appeals Informative Opinion Ex parte Langemyr et al. (Appeal 2008-1495).

Claims 45, 46, 48, 49, 51 and 52 are directed to a method. To qualify as a statutory process, the claim should positively recite the other statutory class to which it is tied, for example by identifying the apparatus, i.e. computer, network, computer-readable medium, etc., that accomplishes the method steps or positively reciting the subject matter that is being transformed, for example by identifying the material that is being changed to a different state. As currently written the steps recited in the claims may be performed by hand or mentally and are therefore not sufficiently tied to another statutory class.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. **Claims 33, 37, 39-46, 48 and 52** are rejected under 35 U.S.C. 102(e) as being anticipated by Gibson (U.S. Pre-Grant Publication Number 2004/0172285), hereinafter Gibson.

As per **claim 33**, Gibson discloses an [a]*pparatus for determining health effect of a selected product, or product(s) providing a selected health effect, the apparatus comprising:*

- *a database of products and associated health effects, the database comprising information on synergistic effects of some or all of the products in the database and counterproductive effects of some or all of the products in the database, when combined with another product or products* (see at least Gibson, Fig. 7 and corresponding text)*;*
- *an input for a user to input the selected product or selected health effect* (see at least Gibson, Fig. 2, #202 and Fig. 8, #802a-f and #804, and corresponding text)*;*
- *a processor for determining health effect of the selected product from the database and/or for determining product(s) from the database providing the selected health effect* (see at least Gibson, Fig. 3, #302 and Fig. 8, #809, and corresponding text)*; and*
- *an output for outputting information to the user* (see at least Gibson, Fig. 2, #202 and corresponding text)*.*

As per the limitation *a database of products and associated health effects*, Gibson discloses information on "drug interactions". Mosby's Dental Dictionary, 2nd edition, defines a "drug interaction" as "a modification of the effect of a drug when administered with another drug. The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either drug." Therefore, information on "drug interactions" would include i*nformation on synergistic effects … and counterproductive effects of some or all of the products*.

As per **claim 37**, Gibson discloses the apparatus of claim 33, discussed above. Gibson further discloses an apparatus *wherein the database comprises at least one of the following* (emphasis added)*:*

- *a) information on the daily consumption quantity for some or all of the products in the database, required to produce the health effect;*
- *b) price of some or all the products in the database; or*
- *c) information on the biologically active chemical or chemicals producing the health effect in some or all the products in the database* (see at least Gibson, paragraphs 44-51)*.*

As per **claim 39**, Gibson discloses the apparatus of claim 37, discussed above. Gibson further discloses an apparatus *wherein the database comprises information on the content of biologically active chemical(s) in each product* (see at least Gibson, paragraphs 44-51)*.*

As per **claims 40-44**, Gibson discloses the apparatus of claim 33, discussed above. Gibson further discloses an apparatus *wherein the processor is a computer, wherein the database is stored on a storage device for use with the computer, wherein the database is stored on the computer hard drive, wherein the input is a computer user interface,* and *wherein the output is a computer user interface* (see at least Gibson, Figures 2-4

and corresponding text).

As per **claim 45**, Gibson discloses a *method for determining health effect of a selected product, or product(s) providing a selected health effect, the method comprising the steps of:*

- *providing a database of products and associated health effects, the database comprising information on synergistic effects of some or all of the products in the database and counterproductive effects of some or all of the products in the database, when combined with another product or products* (see at least Gibson, Fig. 7 and corresponding text)*;*
- *inputting the selected product or selected health effect into a user input* (see at least Gibson, Fig. 2, #202 and Fig. 8, #802a-f and #804, and corresponding text)*;*
- *determining health effect of the selected product from the database, or product(s) from the database providing the selected health effect* (see at least Gibson, Fig. 3, #302 and Fig. 8, #809, and corresponding text)*; and*
- *outputting information to the user* (see at least Gibson, Fig. 2, #202 and corresponding text)*.*

As per the limitation *a database of products and associated health effects*, Gibson discloses information on "drug interactions". Mosby's Dental Dictionary, 2nd edition, defines a "drug interaction" as "a modification of the effect of a drug when administered

with another drug. The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either drug." Therefore, information on "drug interactions" would include i*nformation on synergistic effects … and counterproductive effects of some or all of the products*.

As per **claim 46**, Gibson discloses the method of claim 45, discussed above. Gibson further discloses a method *wherein the step of inputting comprises at least one of the following* (emphasis added)*:*

- *a) selecting the product or health effect from a pre-determined list* (see at least Gibson, Fig. 8, #807 and corresponding text)*;*
- *b) typing the health effect or product name* (see at least Gibson, Fig. 8, #804 and corresponding text)*;*
- *c) scanning a product barcode;*
- *d) inputting the weight of a product;*
- *e) inputting a chemical name;*
- *f) inputting a chemical CAS number; or*
- *g) inputting information on the source of the product.*

As per **claim 48**, Gibson discloses the method of claim 45, discussed above. Gibson further discloses a method *wherein the step of providing a database of products and associated health effects, comprises providing a database including at least one of the*

following (emphasis added)*:*

- *a) information on the daily consumption quantity for some or all of the products in the database, required to produce the health effect;*
- *b) price of some or all the products in the database;*
- *c) information on the biologically active chemical or chemicals producing the health effect in some or all the products in the database* (see at least Gibson, paragraphs 44-51)*;*
- *d) information on the CAS number of biologically active chemical(s) in the products; or*
- *e) information on the content of biologically active chemical(s) in each product* (see at least Gibson, paragraphs 44-51)*.*

As per **claim 52**, Gibson discloses a *method for determining health effect of a selected product, or product(s) providing a selected health effect, the method comprising the steps of:*

- *user computer means receiving an input on the selected product or selected health effect* (see at least Gibson, Fig. 2, #202 and Fig. 8, #802a-f and #804, and corresponding text)*;*
- *host computer means determining, from a database of products and associated health effects, health effect of the selected product, or product(s) providing the selected health effect, the database comprising information on synergistic effects*

of some or all of the products in the database and counterproductive effects of some or all of the products in the database, when combined with another product or products (see at least Gibson, Fig. 7 and corresponding text)*; and*

- *user computer means outputting information to a user* (see at least Gibson, Fig. 2, #202 and corresponding text).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. **Claims 34-36, 38 and 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson, in view of Ellis et al. (U.S. Patent Number 6,654,736 B1), hereinafter Ellis.

As per **claims 34, 35 and 47**, Gibson discloses the apparatus and method of claims 33, 33 and 46, respectively, as discussed above. Gibson fails to disclose, but Ellis succeeds in disclosing an apparatus *further comprising weighing scales connected to the input, for weighing the selected product* and *wherein the weighing scales comprise a user display connected to the output* (see at least Gibson, Fig. 11 and corresponding

text). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Gibson with the chemical information system of Ellis because to do so would result in a system for selecting drugs that "provides database management and communications support for the utilization of all chemistry, inventory, and biology information associated with an organization's drug development program" (Ellis, Col. 1, lines 36-40).

As per **claim 36**, Gibson discloses the apparatus of claim 33, discussed above. Gibson fails to disclose, but Ellis succeeds in disclosing an apparatus *further comprising a barcode scanner connected to the input, for scanning a barcode of the selected product* (see at least Ellis, Fig. 12 and corresponding text). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Gibson with the chemical information system of Ellis because to do so would result in a system for selecting drugs that "provides database management and communications support for the utilization of all chemistry, inventory, and biology information associated with an organization's drug development program" (Ellis, Col. 1, lines 36-40).

As per **claim 38**, Gibson discloses the apparatus of claim 37, discussed above. Gibson fails to disclose, but Ellis succeeds in disclosing an apparatus *wherein the database comprises information on the CAS number of biologically active chemical(s) in the products* (see at least Ellis, Col. 6, lines 17-32). It would have been obvious to one of

ordinary skill in the art at the time of the invention to combine the teachings of Gibson with the chemical information system of Ellis because to do so would result in a system for selecting drugs that "provides database management and communications support for the utilization of all chemistry, inventory, and biology information associated with an organization's drug development program" (Ellis, Col. 1, lines 36-40).

16. **Claims 49-51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson, in view of Schaper et al. ("Computer Programs for Calculation of Median Effective Dose Using the Method of Moving Average Interpolation" Arch Toxicol (1994) 68: 332-37), hereinafter Schaper.

As per **claim 49**, Gibson discloses a method *wherein the database is generated by the method comprising the steps of:*

- *a) providing a first database of products and the contents of biologically active chemicals in those products* (see at least Gibson, paragraphs 44-51)*;*
- *b) providing a second database of biologically active chemicals and … doses of those chemicals required to provide particular health effects* (see at least Gibson, paragraphs 54 and 58)*;*
- *c) selecting a product P from the first database* (see at least Gibson, paragraph 44)*;*

- *d) from the first database, determining a biologically active chemical B in product P and the content C of biologically active chemical B in product P* (see at least Gibson, paragraphs 44-51)*;*
- *e) from the second database, determining the … dose D of biologically active chemical B to provide a particular health effect H* (see at least Gibson, paragraphs 54-58)*;*
- *f) determining the daily consumption quantity DCQ of product P required to provide health effect H, from the results at steps d) and e)* (see at least Gibson, paragraphs 44-60). Examiner notes that it is old and well known in the pharmaceutical arts to determine the daily consumption quantity of an active chemical used to provide a health effect. As an example, see the usage instructions provided with prescribed or over-the-counter medications.
- *g) inputting product P, daily consumption quantity DCQ, biologically active chemical B, content C, … dose D and health effect H into a third database* (see at least Gibson, paragraphs 44-60)*; and*
- *h) repeating one or more of steps c) to g)* (see at least Gibson, paragraphs 44-60)*.*

As per limitations *b)*, *e)* and *g)* Gibson discloses information regarding the minimum dosage, maximum dosage and pregnancy dosage of a biologically active ingredient. Gibson fails to explicitly disclose the *median effective dose*. However, Schaper

discloses the use of the *median effective dose* (see at least Schaper, page 336). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Gibson with the method for calculating the median effective dose of Schaper because to do so would result in a system for selecting drugs in which the "ED_{50} (median effective dose) or LD_{50} and its associated 95% confidence intervals are automatically generated" (Schaper, right column, page 333, parens added).

As per **claims 50 and 51**, Gibson discloses the apparatus and method of claims 33 and 45, respectively, as discussed above. Gibson further discloses an apparatus and method *wherein the database is generated by the method comprising the steps of:*

- *a) providing a first database of products and the contents of biologically active chemicals in those products* (see at least Gibson, paragraphs 44-51)*;*
- *b) providing a second database of biologically active chemicals and … doses of those chemicals required to provide particular health effects* (see at least Gibson, paragraphs 54 and 58)*;*
- *c) selecting a product P from the first database* (see at least Gibson, paragraph 44)*;*
- *d) from the first database, determining a biologically active chemical B in product P and the content C of biologically active chemical B in product P* (see at least Gibson, paragraphs 44-51)*;*
- *e) from the second database, determining the … dose D of biologically active*

chemical B to provide a particular health effect H (see at least Gibson, paragraphs 54-58)*;*

- *f) determining the daily consumption quantity DCQ of product P required to provide health effect H, from the results at steps d) and e)* (see at least Gibson, paragraphs 44-60). Examiner notes that it is old and well known in the pharmaceutical arts to determine the daily consumption quantity of an active chemical used to provide a health effect. As an example, see the usage instructions provided with prescribed or over-the-counter medications.
- *g) inputting product P, daily consumption quantity DCQ, biologically active chemical B, content C, … dose D and health effect H into a third database* (see at least Gibson, paragraphs 44-60)*; and*
- *h) repeating one or more of steps c) to g)* (see at least Gibson, paragraphs 44-60)*.*

As per limitations *b)*, *e)* and *g)* Gibson discloses information regarding the minimum dosage, maximum dosage and pregnancy dosage of a biologically active ingredient. Gibson fails to explicitly disclose the *median effective dose*. However, Schaper discloses the use of the *median effective dose* (see at least Schaper, page 336). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Gibson with the method for calculating the median effective dose of Schaper because to do so would result in a system for selecting drugs in which

the "ED_{50} (median effective dose) or LD_{50} and its associated 95% confidence intervals are automatically generated" (Schaper, right column, page 333, parens added).

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

18. Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Mark Holcomb,** whose telephone number is **571.270.1382.** The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm.

19. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **Jerry O'Connor,** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair

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/M. H./
Examiner
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Art Unit 3686

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